K090042

MAY - 6 2009

5.0 510(k) Summary

The following information is provided as required by 21 CFR §§ 807.87 and 807.92 for Newmark, Inc.'s 510(k) premarket notification. The following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor Newmark Inc.
182 Sandbank Road
Cheshire, CT 06410

Manufacturer Newmark Inc.
182 Sandbank Road
Cheshire, CT 06410
Registration Number: 1226514

Contact: Deborah Livornese
Buc & Beardsley
919 Eighteenth Street, N.W., Suite 600
Washington, D.C. 20006
Phone: 202.736.3622
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dlivornese@bucbeardsley.com

Date Prepared: 12/30/08

Proposed Class: II

Proprietary Name: Painmaster MCT Patch

Common Name: Transcutaneous electrical nerve stimulator for pain relief

Classification Name: Stimulator, nerve, transcutaneous, over-the-counter

Regulation Number: 21 CFR 882.5890

Product Code: NUH

Predicate Devices: K013167 – Model 7500 Microcurrent TENS Device (Version F5) (same device as subject for prescription use)
K033122 – Prizm Medical 5000Z System (OTC), and
K060222 – Gemore Technology Low Back Pain Relief System (OTC).

Intended Use

The Painmaster MCT Patch is indicated for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities. This intended use is a subset of the intended use for the device when it was cleared for prescription use, and is also identical to that of other OTC cleared TENS devices.

Device Description

The Painmaster MCT Patch operates in a single non-programmable microcurrent mode, delivering a pulsed monophasic waveform that provides electrical stimulation to the body to relieve pain.

The Painmaster MCT Patch consists of two electrodes mounted on adhesive material connected by a small-diameter wire. One electrode contains the control unit that includes a small circuit board, a battery, and an LED light.

Technological Characteristics

The technological characteristics of the Painmaster MCT Patch are identical to one of the devices (the F-5 version) cleared under K013167.

Performance Testing

Additional performance testing was not required to determine the substantial equivalence of this device for OTC use because the device is the same as the device previously cleared for prescription use via 510(k) #K013167.

Usability Study

A usability study was conducted and demonstrated that users could correctly identify themselves as candidates for treatment, and could properly assemble and apply the device according to the instructions for use. The Final Study Report for the Usability Study is attached as Exhibit 6.

Conclusion

The Painmaster MCT Patch is substantially equivalent to legally marketed devices because it has the same technological characteristics and the same intended use as predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

Newmark, Inc.
% Ms. Deborah Livornese
Buc & Beardsley
919 Eighteenth St. NW, Suite 600
Washington, DC 20006

Re: K090042
Trade/Device Name: Painmaster MCT Patch
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Code: NUH
Dated: March 24, 2009
Received: March 30, 2009

Dear Ms. Livornese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for David Krause

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number: To be assigned

Device Name: **Painmaster MCT Patch**

Indications for Use:

The Painmaster MCT Patch is indicated for temporary relief of pain associated with sore and aching muscles in the lower back due to strain from exercise or normal household and work activities.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090042

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